IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL, SRL, and ORTHO-MCNEIL, INC., Plaintiffs/Counterclaim-defendants, v. PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC., Defendants/Counterclaim-plaintiffs.	C.A. No. 07-255-JJF (CONSOLIDATED)

DECLARATION OF KEVIN J. SMITH IN SUPPORT OF PLAINTIFFS' OPENING BRIEF ON CLAIM CONSTRUCTION

I, Kevin J. Smith, declare pursuant to 28 U.S.C. § 1746 that:

1. I reside in Cambridgeshire, England. I am employed by Mundipharma Research Limited and my current title is Head of Clinical Pharmacology - Europe. I have been employed by this company that has had various names since 1986. I refer to Napp Research Centre, Napp Laboratories Ltd., Mundipharma Research Ltd., and Napp Pharmaceutical Group Ltd. collectively as "Napp."

2. I earned a B.Sc. degree in Pharmacology from the University of Aberdeen in 1980 and a Ph.D. degree in Pharmacology from the University of Aberdeen in 1984.

3. I understand that, in this lawsuit, a group of companies including Napp contend that proposed generic copies of ULTRAM® ER controlled release Tramadol tablets

infringe certain claims in U.S. Patent No. 6,254,887 ("'887 patent") and U.S. Patent No. 7,074,430 ("'430 patent") (collectively "the patents in suit"). I am one of the co-inventors of the patents in suit.

4. I make this declaration in support of Plaintiffs' proposed claim constructions, to provide a brief tutorial to the Court to explain the process of drug development of new pharmaceutical formulations in industry. I also describe briefly the development history of controlled release tramadol at Napp and Mundipharma GmbH that led to the applications for the patents in suit. My declaration is based on my personal knowledge and professional experience.

THE DRUG DEVELOPMENT PROCESS

5. Drug development of new formulations is a costly and time consuming process. Each successive step of the process requires increased resources, including funds and manpower, from the company sponsoring the development.

6. The first step is to identify a suitable active ingredient and a target for how that active ingredient will behave when administered to patients. Following that, an iterative process begins between the chemists who attempt to develop a formulation ("formulators") to meet those goals and the other scientists and doctors ("clinicians") responsible for determining whether an experimental formulation is safe for testing on humans and whether it shows sufficient promise to proceed to the next stage of development.

7. Clinical testing in humans is called *in vivo* testing. One type of *in vivo* test measures the blood plasma level of the active ingredient in healthy test subjects over a period of time after dosing. This is called "bioavailability" testing. If the formulation fails bioavailability testing, the iterative process of re-formulation and *in vitro* testing begins again. If a formulation

provides the target blood plasma levels, then the company may decide to commit resources to proceed to later stages of clinical trials.

THE MAKING OF THE INVENTIONS OF THE PATENTS IN SUIT

8. The initial formulation work on controlled release tramadol described in the patents in suit was carried out by scientists at Mundipharma GmbH in Germany, an independent company associated with Napp. My colleagues and I at Napp were regularly kept informed of the progress of that work.

9. In the early 1990s my colleagues at Napp and I supported *in vivo* testing of a 12-hour formulation developed at Mundipharma GmbH. By "12-hour formulation" I mean a controlled-release formulation intended to have therapeutic effect for 12 hours, so that it could be administered to patients twice a day. Such a formulation was believed to be an advance over then-available immediate release tramadol formulations, which were administered every six hours, or four times daily.

10. At about the same time, scientists at Napp were also working on a 24-hour formulation. This work included a target blood plasma profile, and involved estimation of the *in vitro* dissolution ranges that might produce the target profile.

11. The patents in suit describe the work of both the Napp and Mundipharma GmbH groups on controlled release tramadol formulations.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct. Executed on June 13th, 2008 in Cambridge, England.

KEVIN J. SMITH

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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I further certify that I caused to be served copies of the foregoing document on June 13, 2008, upon the following in the manner indicated:

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/s/ Rodger D. Smith II

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